EXHIBIT A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BARBARA GAYLE, individually, NORMA CLARK, individually, LAURA FLORES, individually, DOROTHY JONES, individually, ROSALIE BUONAMANO and ARNOLD BUONAMANO, individually and as husband and wife, CAROL MEIDL and EDWARD MEIDL, individually and as husband and wife, CHRISTIE KELLY, individually, PEARLY COLEMAN, individually, MARA SCOTT and RONNIE SCOTT, individually and as husband and wife, CHERRY RICHARDSON, individually, CHERYL DORSEY, individually, TAMMY AXELROD and BRYAN AXELROD, individually and as husband and wife, CHARLIE JOHNSON, individually, TAWNYA LOCKHART, individually, LEONA RHETT and TOMMIE A. RHETT, individually and as husband and wife, JACQUELYN LOVETT, individually, SHARON STEWART, individually, SHENNA ALBERT ,individually and CARLETHA FOSTER, individually

Plaintiffs,

vs.

PFIZER, INC.; MCKESSON CORPORATION; and DOES 1-50,

Defendants.

CASE NO.: 1:19-CV-03451
HON: WILLIAM H. PAULEY III

[PROPOSED] FIRST AMENDED COMPLAINT FOR DAMAGES

DEMAND FOR JURY TRIAL

For their Complaint against the Defendants, Plaintiffs allege:

PARTIES AND JURISDICTION

1. Plaintiff BARBARA GAYLE is, and at all relevant time was, a citizen and resident of the State of MINNESOTA. Plaintiff BARBARA GAYLE brings this action for personal injuries sustained by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff BARBARA GAYLE was diagnosed with Diabetes Mellitus Type II.

2. Plaintiff NORMA CLARK is, and at all relevant time was, a citizen and resident of the State of FLORIDA. Plaintiff NORMA CLARK brings this action for personal injuries sustained by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff NORMA CLARK was diagnosed with Diabetes Mellitus Type II.

3. Plaintiff LAURA FLORES is, and at all relevant time was, a citizen and resident of the State of FLORIDA. Plaintiff LAURA FLORES brings this action for personal injuries sustained by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff LAURA FLORES was diagnosed with Diabetes Mellitus Type II.

4. Plaintiff DOROTHY JONES is, and at all relevant time was, a citizen and resident of the State of FLORIDA. Plaintiff DOROTHY JONES brings this action for personal injuries sustained by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff DOROTHY JONES was diagnosed with Diabetes Mellitus Type II.

5. Plaintiff ROSALIE BUONAMANO is, and at all relevant time was, a citizen and resident of the State of FLORIDA. Plaintiff ROSALIE BUONAMANO brings this action for personal injuries sustained by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff ROSALIE BUONAMANO was diagnosed with Diabetes Mellitus Type II.

6. Plaintiff ARNOLD BUONAMANO at all times relevant to this action was and is a citizen and resident of the State of FLORIDA. Plaintiffs ARNOLD BUONAMANO and ROSALIE BUONAMANO. were and are, at all times relevant to this action, legally married as husband and wife. Plaintiff ARNOLD BUONAMANO brings this action for, *inter alia*, the loss of consortium, comfort, and society he suffered due to the personal injuries suffered by his wife, ROSALIE BUONAMANO.

7. Plaintiff CAROL MEIDL is, and at all relevant time was, a citizen and resident of the State

of MINNESOTA. Plaintiff CAROL MEIDL brings this action for personal injuries sustained by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff CAROL MEIDL was diagnosed with Diabetes Mellitus Type II.

8. Plaintiff EDWARD MEIDL at all times relevant to this action was and is a citizen and resident of the State of MINNESOTA. Plaintiffs CAROL MEIDL and EDWARD MEIDL. were and are, at all times relevant to this action, legally married as husband and wife. Plaintiff EDWARD MEIDL brings this action for, *inter alia*, the loss of consortium, comfort, and society he suffered due to the personal injuries suffered by his wife, CAROL MEIDL.

9. Plaintiff CHRISTIE KELLY is, and at all relevant time was, a citizen and resident of the State of FLORIDA. Plaintiff CHRISTIE KELLY brings this action for personal injuries sustained by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff CHRISTIE KELLY was diagnosed with Diabetes Mellitus Type II.

10. Plaintiff PEARLY COLEMAN is, and at all relevant time was, a citizen and resident of the State of FLORIDA. Plaintiff PEARLY COLEMAN brings this action for personal injuries sustained by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff PEARLY COLEMAN was diagnosed with Diabetes Mellitus Type II.

11. Plaintiff MARA SCOTT is, and at all relevant time was, a citizen and resident of the State of FLORIDA. Plaintiff MARA SCOTT brings this action for personal injuries sustained by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff MARA SCOTT was diagnosed with Diabetes Mellitus Type II.

12. Plaintiff RONNIE SCOTT at all times relevant to this action was and is a citizen and resident of the State of FLORIDA. Plaintiffs MARA SCOTT and RONNIE SCOTT. were and are, at all times relevant to this action, legally married as husband and wife. Plaintiff RONNIE

SCOTT brings this action for, *inter alia*, the loss of consortium, comfort, and society he suffered due to the personal injuries suffered by his wife, MARA SCOTT.

13. Plaintiff CHERRY RICHARDSON is, and at all relevant time was, a citizen and resident of the State of FLORIDA. Plaintiff CHERRY RICHARDSON brings this action for personal injuries sustained by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff CHERRY RICHARDSON was diagnosed with Diabetes Mellitus Type II.

14. Plaintiff CHERYL DORSEY is, and at all relevant time was, a citizen and resident of the State of FLORIDA. Plaintiff CHERYL DORSEY brings this action for personal injuries sustained by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff CHERYL DORSEY was diagnosed with Diabetes Mellitus Type II.

15. Plaintiff TAMMY AXELROD is, and at all relevant time was, a citizen and resident of the State of FLORIDA. Plaintiff TAMMY AXELROD brings this action for personal injuries sustained by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff TAMMY AXELROD was diagnosed with Diabetes Mellitus Type II.

16. Plaintiff BRYAN AXELROD at all times relevant to this action was and is a citizen and resident of the State of FLORIDA. Plaintiffs TAMMY AXELROD and RONNIE AXELROD. were and are, at all times relevant to this action, legally married as husband and wife. Plaintiff RONNIE AXELROD brings this action for, *inter alia*, the loss of consortium, comfort, and society he suffered due to the personal injuries suffered by his wife, TAMMY AXELROD.

17. Plaintiff CHARLIE JOHNSON is, and at all relevant time was, a citizen and resident of the State of MINNESOTA. Plaintiff CHARLIE JOHNSON brings this action for personal injuries sustained by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff CHARLIE JOHNSON was diagnosed with Diabetes Mellitus Type II.

18. Plaintiff TAWYNA LOCKHART is, and at all relevant time was, a citizen and resident of the State of WYOMING. Plaintiff TAWYNA LOCKHART brings this action for personal injuries sustained by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff TAWYNA LOCKHART was diagnosed with Diabetes Mellitus Type II.

19. Plaintiff LEONA RHETT is, and at all relevant time was, a citizen and resident of the State of FLORIDA. Plaintiff, LEONA RHETT brings this action for personal injuries sustained by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff LEONA RHETT was diagnosed with Diabetes Mellitus Type II.

20. Plaintiff TOMMIE A. RHETT at all times relevant to this action was and is a citizen and resident of the State of FLORIDA. Plaintiffs LEONA RHETT and TOMMIE A. RHETT. were and are, at all times relevant to this action, legally married as husband and wife. Plaintiff TOMMIE A. RHETT brings this action for, *inter alia*, the loss of consortium, comfort, and society he suffered due to the personal injuries suffered by his wife, LEONA RHETT.

21. Plaintiff JACQUELYN LOVETT is, and at all relevant time was, a citizen and resident of the State of FLORIDA. Plaintiff JACQUELYN LOVETT brings this action for personal injuries sustained by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff JACQUELYN LOVETT was diagnosed with Diabetes Mellitus Type II.

22. Plaintiff SHARON STEWART is, and at all relevant time was, a citizen and resident of the State of MISSOURI. Plaintiff SHARON STEWART brings this action for personal injuries sustained by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff SHARON STEWART was diagnosed with Diabetes Mellitus Type II.

23. Plaintiff SHENNA ALBERT is, and at all relevant time was, a citizen and resident of the State of MAINE. Plaintiff SHENNA ALBERT brings this action for personal injuries sustained

by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff SHENNA ALBERT was diagnosed with Diabetes Mellitus Type II.

24. Plaintiff CARLETHA FOSTER is, and at all relevant time was, a citizen and resident of the State of MISSOURI. Plaintiff CARLETHA FOSTER brings this action for personal injuries sustained by the use of LIPITOR® (atorvastatin calcium), and as a direct and proximate result of being prescribed and ingesting LIPITOR®, Plaintiff CARLETHA FOSTER was diagnosed with Diabetes Mellitus Type II.

25. The Defendant PFIZER, INC., (hereafter referred to as "PFIZER") is a corporation or business entity organized and existing under the laws of the State of Delaware, with its principal place of business in New York, New York.

26. At all relevant times, Defendant PFIZER, INC. transacted business in the State of NEW YORK and derives substantial income from doing business in this state.

27. Defendant MCKESSON CORPORATION was and is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Post Street, San Francisco, NEW YORK 94104. MCKESSON CORPORATION touts itself as, among other things: (1) the largest pharmaceutical distributor in North America distributing one-third of the medications used daily in North America, (2) the nation's leading health care information technology company, and (3) a provider of "decision support" software to help physicians determine the best possible clinical diagnosis and treatment plans for patients.

28. At all relevant times, Defendant MCKESSON CORPORATION conducted regular and sustained business in NEW YORK by selling and distributing its products and services in NEW YORK and engaged in substantial commerce and business activities in all counties of NEW YORK.

29. The true names or capacities, whether individual, corporate, or otherwise, of Defendants Does 1-50, are unknown to Plaintiffs who therefore sue said Defendants by such fictitious names. Plaintiffs believe and allege that each of the Defendants designated herein by fictitious

names is in some manner legally responsible for the events and happenings herein referred to and proximately caused foreseeable damages to Plaintiffs as alleged herein.

30. All Defendants are authorized to do business in NEW YORK and derive substantial income from doing business in this state.

31. As used herein, "Defendants" includes all named Defendants as well as Does 1-50.

32. Upon information and belief, Defendants did act together to design, sell, advertise, manufacture and /or distribute LIPITOR®, with full knowledge of its dangerous and defective nature.

33. This court has personal jurisdiction over the Defendants named herein because said Defendants have sufficient minimum contacts with the forum state upon which to predicate personal jurisdiction.

GENERAL ALLEGATIONS

34. This is a civil action brought on behalf of Plaintiffs regarding damages that were proximately caused by the ingestion of LIPITOR® by Plaintiffs. These individuals are referred to herein as "Plaintiffs."

35. The State of NEW YORK has a substantial interest in assuring that the acts of these Defendants who have been given the privilege of doing business in its borders act in conformity with all laws applicable to the acts as set forth in this Complaint.

36. At all times relevant herein, Defendants were in the business of designing, testing, manufacturing, labeling, advertising, marketing, testing, promoting, selling and distributing pharmaceuticals, including LIPITOR®, and other products for use by the mainstream public, including Plaintiffs.

37. LIPITOR® was designed, manufactured, marketed, distributed and sold to the Plaintiffs by one or more Defendants, and more specifically, upon information and belief, Defendant McKesson did distribute the LIPITOR® Plaintiffs ingested, which gives rise to the causes of action and the injuries sustained as a direct and proximate result of such ingestion.

38. LIPITOR® is prescribed to reduce the amount of cholesterol and other fatty substances in

the blood.

39. Parke-Davis Pharmaceutical Research, a division of Warner-Lambert Company obtained approval from the Food and Drug Administration ("FDA") to market LIPITOR® on December 17, 1996. Warner-Lambert entered into a co-marketing agreement with Pfizer to sell LIPITOR®, and thereafter those companies began distributing and selling LIPITOR® throughout the United States in 1997. On June 19, 2000, Pfizer acquired Warner-Lambert and all rights to LIPITOR®.

40. Despite its knowledge of data indicating that LIPITOR® use is causally related to the development of type 2 diabetes and/or blood glucose levels diagnostic for type 2 diabetes, Pfizer promoted and marketed LIPITOR® as safe and effective for persons such as Plaintiffs throughout the United States, including in the State of NEW YORK.

41. LIPITOR® represented approximately 25 percent of Defendant's annual revenue between 2001 and 2011.

42. Pfizer spent approximately $1.5 billion in advertising directly to consumers.

43. Before its patent expired, Defendant spent over $600 million per year to market LIPITOR.

44. At the time the FDA approved LIPITOR, there were at least four safe and effective statin drugs on the market and at least five drugs that safely and effectively lowered cholesterol.

45. On August 11, 2011, the Division of Metabolism and Endocrinology Products of the FDA requested that Defendant Pfizer make labeling changes for LIPITOR® based upon the FDA's comprehensive review, including clinical trial data.

46. In February 2012, Pfizer added the following language to its Warnings and Precautions Section: "Increases in HbAlc and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including LIPITOR®."

47. Until the February 2012 change, LIPITOR's label had never warned patients of any potential relation between changes in blood sugar levels and taking LIPITOR

48. Despite the February 2012 label change, LIPITOR®'s label continued to fail to clearly warn consumers of the serious risk of developing type 2 diabetes *per se* when using LIPITOR®.

49. By definition, "Type 2 diabetes" is both more specific and more severe that "Increases in

HbA1c. As such, in accordance with 21 C.F.R. § 314.80(a), Type II Diabetes is an unexpected adverse drug experience.

50. At no time did Defendants seek to add Type II Diabetes to the package insert via Changes Being Effected as allowed under 21 C.F.R. § 314.70(c)(6)(iii)(A).

51. At no time did Defendants request via a prior approval supplement that the FDA allow Defendants to add a warning for Type II Diabetes, despite ever-increasing evidence concerning the possible relationship between LIPITOR® and Type II Diabetes.

52. At all times material hereto, Defendants knew or should have known that the risks of LIPITOR® included the severe and life-threatening complications of type 2 diabetes.

53. At all times material hereto, Defendants, by and through their agents, servants, and/or employees, negligently, recklessly and/or carelessly marketed, distributed, and/or sold LIPITOR® without adequate instructions or warnings of the drug's serious side effects and unreasonably dangerous risks.

54. LIPITOR® is rapidly absorbed after oral administration; maximum plasma concentrations occur within 1 to 2 hours. The absolute bioavailability of atorvastatin (parent drug) is approximately 14% and the systemic availability of HMG-CoA reductase inhibitory activity is approximately 30%.

55. The absorption and bioavailability of LIPITOR® differs substantially depending on the patient profile, including whether a patient is male or female, and the age of the patient.

56. LIPITOR® has not been shown to be effective in women.

57. Mean plasma elimination half-life of LIPITOR® in humans is approximately 14 hours, but the half-life of inhibitory activity for HMG-CoA reductase is 20 to 30 hours due to the contribution of active metabolites.

58. Defendants sold or aided and abetted in the sale of LIPITOR® which was and is defective and unreasonably dangerous. At all pertinent times, Defendants knew or should have known, that LIPITOR® was and is hazardous to human health.

59. Defendants, through their funding and control of certain studies concerning the effects of LIPITOR® on human health, their control over trade publications, promoting, marketing, and/or through other agreements, understandings and joint undertakings and enterprises, conspired with, cooperated with and/or assisted in the wrongful suppression, active concealment and/or misrepresentation of the true relationship between LIPITOR® and type 2 diabetes, to the detriment of the public health, safety and welfare and thereby causing harm to the State.

60. Specifically, and in addition to the allegations above, Defendants knew of the hazards associated with LIPITOR®; affirmatively and actively concealed information which clearly demonstrated the dangers of LIPITOR® and affirmatively misled the public and prescribing physicians with regard to the material and clear risks of LIPITOR® with the intent that prescribing physicians would continue to prescribe LIPITOR®. Defendants well knew that prescribing physicians would not be in a position to know the true risks of LIPITOR® and Defendants knew that prescribing physicians would rely upon the misleading information that they promulgated.

61. At all pertinent times, Defendants purposefully and intentionally engaged in these activities, and continue to do so, knowing full well that when the general public, including Plaintiffs, use LIPITOR® as Defendants intended, that Plaintiffs would be substantially certain to suffer disease, injury, and sickness.

62. The statements, representations and promotional schemes publicized by Defendants were deceptive, false, incomplete, misleading and untrue. Defendants knew or should have known, that their statements, representations, and advertisements were deceptive, false, incomplete, misleading and untrue at the time of making such statements. Defendants had an economic interest in making such statements. Neither the Plaintiffs nor the physicians who prescribed LIPITOR® to them had knowledge of the falsity or untruth of Defendants' statements, representations, and advertisements when prescriptions for LIPITOR® were written. Moreover, Plaintiffs and Plaintiffs' physicians had a right to rely on Defendants' statements, representations, and advertisements. Each of the statements, representations, and advertisements were material to the Plaintiffs' purchase of LIPITOR® in that the Plaintiffs would not have purchased LIPITOR® if Plaintiffs had known that

Defendants' statements, representations, and advertisements were deceptive, false, incomplete, misleading and untrue. These acts were designed to and did, in fact, allow Defendants to earn substantial income from the sale of LIPITOR®.

63. Plaintiffs had a right to rely upon the representations of Defendants and were directly and proximately injured by such reliance, all as described above.

64. Had Plaintiffs been adequately warned of the increased risk of injuries and life-threatening side effects, they would have chosen to request other prescription medications and avoided LIPITOR®'s injuries and potentially life-threatening side effects.

65. Even if the Plaintiff and their health care professionals were willing to prescribe/ingest LIPITOR®, Plaintiff and their physicians would have been better able to manage and mitigate the risks of Type II Diabetes had Defendants properly warned of the relationship.

66. Plaintiffs were prescribed LIPITOR® by a physician(s) authorized to prescribe LIPITOR®, ingested LIPITOR® as prescribed, and as a result, suffered damages and injury.

67. Plaintiffs were prescribed LIPITOR® and used it as directed.

68. Plaintiffs were prescribed LIPITOR® to lower their levels of low-density lipoprotein ("LDL").

69. Plaintiffs agreed to initiate LIPITOR® treatment in an effort to reduce their risk of developing heart disease.

70. Plaintiffs developed type 2 diabetes after initiating their LIPITOR® treatment.

71. Plaintiffs were diagnosed with type 2 diabetes while still taking LIPITOR®. As a result, for the rest of their lives they must undergo regular testing of their blood glucose levels, adhere to a restrictive diabetic diet, and take medication to control their diabetes, due to their diabetes, they are now at a markedly increased risk of heart disease, blindness, neuropathy, and kidney disease.

72. Defendants negligently, recklessly and wantonly failed to warn Plaintiffs, Plaintiffs' physicians, and the general public, of the risks associated with taking LIPITOR®. Defendants failed to do so even after various studies, including their own, showed that there were problems concerning the risk of diabetes associated with LIPITOR®.

73. Defendants endeavored to deceive Plaintiffs, and the general public, by not disclosing the findings of the various studies, including its own that revealed problems concerning the dangers of LIPITOR®.

74. Further, Defendants did not provide warnings and instructions that would have put Plaintiffs and Plaintiffs' physicians, and the general public, on notice of the dangers and adverse effects caused by LIPITOR®.

75. In the European Union, and identified risk is defined as follows:

> **Identified risk**
>
> An untoward occurrence for which there is adequate evidence of an association with the medicinal product of interest. Examples of identified risks include:
>
> - An adverse reaction adequately demonstrated in non-clinical studies and confirmed by clinical data
> - An adverse reaction observed in well-designed clinical trials or epidemiological studies for which the magnitude of the difference, compared with the comparator group (placebo or active substance, or unexposed group), on a parameter of interest suggests a causal relationship
> - An adverse reaction suggested by a number of well-documented spontaneous reports where causality is strongly supported by temporal relationship and biological plausibility, such as anaphylactic reactions or application site reactions.

76. In the European Union, Lipitor (atorvastatin) is an important identified risk for Type II Diabetes at the 10, 20, and 40 mg doses. This information was not shared with U.S. healthcare professionals and patients.

77. Defendants designed, manufactured, distributed, sold and/or supplied LIPITOR® and placed LIPITOR® into the stream of commerce in a defective and unreasonably dangerous condition, taking into consideration the utility of the drug and the risk to Plaintiffs and the general public.

78. LIPITOR® as designed, manufactured, distributed, sold and/or supplied by Defendants was defective as marketed due to inadequate warnings, instructions and/or labeling.

79. LIPITOR® as designed, manufactured, distributed, sold and/or supplied by Defendants was defective due to inadequate testing before and after Defendants' knowledge of the various studies, including their own, evidencing the rightful concerns over the risks of diabetes and diabetes-related injuries associated with LIPITOR®.

80. The nature of the Plaintiffs' injuries and their relationship to LIPITOR® use were inherently undiscoverable; and, consequently, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew or through the exercise of reasonable care and diligence should have known of the existence of their claims against Defendants. Plaintiffs did not discover, and through the exercise of reasonable care and due diligence, could not have discovered, their injuries earlier.

81. Further, Plaintiffs did not have knowledge of facts that would lead a reasonable, prudent person to make an inquiry to discover Defendants' tortious conduct. Under the appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

82. To this day, Defendants deny that there is a relationship between LIPITOR® and Type II Diabetes. Nor is there any warning concerning the relationship in the package insert to this day. As such, it is not generally accepted in the medical community that LIPITOR® causes or contributes to the development of Type II Diabetes.

83. Defendants are estopped from asserting a statute of limitations defense because they fraudulently concealed from Plaintiffs the nature of Plaintiffs' injuries and the connection between the injury and LIPITOR®. Furthermore, to this day Defendants continue to deny that there is any relationship between LIPITOR® and Type II Diabetes.

84. Defendants have over-promoted LIPITOR®, thus eliminating a defense of learned intermediary.

85. LIPITOR® fails to meet reasonable consumer expectations, thus eliminating the defense of learned intermediary.

86. Defendants failed to properly disclose to the FDA and the public, information necessary to

allow an informed decision to be made with regard to the contents of the label and/or the approved uses of LIPITOR®.

87. From July 1, 2012, through June 30, 2015 Defendant Pfizer submitted more than 6,000 adverse event reports to the FDA identifying Diabetes as being an unexpected event for Lipitor. By definition, this means that Diabetes was not in the package insert.

88. On information and belief, this practice continues to this day. As such, Defendant Pfizer cannot argue that Diabetes is in the package insert.

89. Defendants had the duty to review all adverse event information in meeting its safety surveillance obligations under 21 C.F.R. § 314.80(b):

> Review of adverse drug experiences. Each applicant having an approved application under § 314.50 or, in the case of a 505(b)(2) application, an effective approved application, shall promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers. Applicants are not required to resubmit to FDA adverse drug experience reports forwarded to the applicant by FDA; however, applicants must submit all follow up information on such reports to FDA. Any person subject to the reporting requirements under paragraph (c) of this section shall also develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA[1].

90. In accordance with 21 C.F.R. § 314.80(c), not all adverse events are required to be reported to the FDA. Even so, manufacturers are required to review such adverse events in accordance with 21 C.F.R. § 314.80(b) and 21 C.F.R. § 314.81. Furthermore, Pfizer was required to look at all of the information in aggregate.

91. Thus, at all times Pfizer possessed more information than the FDA concerning the relationship between Lipitor and Diabetes.

92. Given the large number of adverse event reports received by Pfizer, internal information only in the possession of Pfizer, and the reasonably available scientific literature Pfizer knew or

[1] 21 C.F.R. § 314.80(b)

should have known that the label as of 2012 was inadequate with respect to the relationship between LIPITOR® and diabetes.

93. At no time did Pfizer change the label with respect to diabetes nor did they petition the FDA for the inclusion of diabetes in the label.

94. While increases in HBA1C are a symptom of diabetes, not every increase in HBA1c means the patient has diabetes. Diabetes is more serious than just increases in HBA1c. Because not every elevation of HBA1c means the individual has diabetes, diabetes is a more specific term than the elevation of HBA1c. Thus the term diabetes is both more specific and more severe that elevation in HBA1c.

95. As such, in accordance with 21 C.F.R. § 314.80(a), diabetes is an unexpected event for LIPITOR®.

96. Because labels are written for patients and their healthcare professionals, the failure to update conduct proper pharmacovigilance and update the labeling has a direct effect on doctors and patients.

97. Despite some information available to the general public concerning the ***question*** as to whether LIPITOR® can cause or contribute to diabetes, this does not establish that it is generally accepted in the science community that LIPITOR® causes diabetes. Furthermore, Defendants continue to deny that there is a relationship.

98. Even with the exercise of proper diligence, it would have been difficult, if not impossible, for Plaintiffs to have determined that Lipitor more likely than not increases the risk of diabetes, particularly in light of Pfizer's denials of such a relationship.

99. Because of Defendants' continued denial of the relationship between LIPITOR® and Type II Diabetes and because Defendants failed to disclose that LIPITOR® is an important identified risk for Diabetes technical, scientific, and medical knowledge and information was insufficient to ascertain the cause of Plaintiffs' injuries and that Plaintiffs were unable to ascertain that LIPITOR® was the cause of their injuries until more than three years after the discovery of their injuries.

100. Furthermore, in earlier proceedings with different counsel, the MDL Court in Charleston, South Carolina dismissed then existing cases because, in that Court's opinion, Plaintiffs had failed to demonstrate that a causal relationship between LIPITOR® and Type II Diabetes was more likely than not. Thus certainly through the time of the Court's ruling, it was not generally accepted that LIPITOR® causes or contributes to the development of Type II Diabetes.

101. Although the package insert is monitored by the FDA and the FDA can require manufacturers such as Pfizer to make changes, the primary responsibility for making labeling changes rests with the manufacturer.

102.

103. For each Cause of Action hereinafter alleged and averred, the above and following Paragraphs should be considered re-alleged as if fully rewritten.

FRAUDULENT CONCEALMENT AND TOLLING

104. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

105. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiffs and their physicians the true risks associated with the use of Lipitor.

106. Despite having internal knowledge that LIPITOR® does increase the risk of developing Type II Diabetes, Defendants continue to deny that there is a relationship.

107. Defendants never shared with U.S. healthcare professionals and patients that LIPITOR® was an important identified risk for Diabetes.

108. As a result of Defendant's actions, Plaintiffs and their physicians were unaware, and could not reasonably have known or have learned through reasonable diligence, that they had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

FIRST CAUSE OF ACTION

(Strict Liability)

109. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

110. Defendants defectively designed and manufactured LIPITOR®, which was marketed to physicians and the general public, including Plaintiffs.

111. Plaintiffs ingested LIPITOR® for the treatment and control of high cholesterol, which was the foreseeable and intended use of LIPITOR®.

112. LIPITOR® failed to perform as safely as an ordinary consumer would expect, as the use of LIPITOR® was associated with an increased risk of severe, physical injury, or death, resulting from type 2 diabetes.

113. The design of LIPITOR® was defective in that the risks associated with using LIPITOR® outweighed any benefits of the design. Any benefits associated with the use of LIPITOR® were relatively minor and could have been obtained by the use of other, alternative treatments and products that could equally or more effectively reach similar results.

114. The defect in design existed when the product left Defendants' possession.

115. At the time LIPITOR® left the control of Defendants, Defendants knew or should have known of the risks associated with ingesting LIPITOR®.

116. At all times material hereto, Defendants failed to provide Plaintiffs the warnings or instructions a manufacturer exercising reasonable care would have provided concerning the risk which ultimately caused Plaintiffs' injuries.

117. At all times material hereto, Defendants failed to provide post-marketing warnings or instructions to Plaintiffs or Plaintiffs' physicians sufficient to convey the true risks associated with the use of LIPITOR®.

118. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs were injured as described above.

WHEREFORE, Plaintiffs demand judgment against Defendants in such an amount

of compensatory and punitive damages as a jury deems reasonable, plus costs.

SECOND CAUSE OF ACTION

(Negligence)

119. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

120. Defendants had a duty to exercise reasonable care in designing, developing, testing, manufacturing, packaging, labeling, marketing, advertising, selling and/or distributing LIPITOR®.

121. Defendants failed to exercise ordinary care in designing, developing, testing, manufacturing, packaging, labeling, marketing, advertising, selling, and/or distributing of LIPITOR®.

122. Defendants knew or should have known that LIPITOR® created an unreasonable risk of bodily harm.

123. Defendants have an ongoing duty of pharmacovigilance. As part of this duty, Defendants are required to continually monitor, test, and analyze data regarding the safety, efficacy, and prescribing practices of its marketed drugs, including LIPITOR ®. Defendant continually received reports from its own clinical trials, practicing physicians, individual patients and regulatory authorities concerning adverse events that occur in patients taking Enbrel® and Defendants' other marketed drugs. Furthermore, Defendants continue to conduct clinical trials for its marketed drugs long after the drug is approved for use. Defendants have a continuing duty to inform doctors, regulatory agencies, and the public of new safety and efficacy information they learn, or should have learned, about their marketed drugs once that information becomes available to Defendants, whether through Defendants' clinical trials, other outside sources or pharmacovigilance activities. Specifically, when Defendants learn or should have learned, of new safety information associated with its marketed drugs, Defendants have a duty to promptly disseminate that data to the public. Defendants also have a continuing duty to monitor epidemiology and pharmacovigilance data

regarding its marketed drugs and promptly report any safety concerns that arise through epidemiologic study or data.

124. Defendants were further negligent and breached this continuing duty of pharmacovigilance with respect to Plaintiff. Defendants, through clinical trials and other adverse event reports, learned that there was a serious problem associated with Enbrel® use and failed to adequately inform doctors, regulatory agencies and the public of this risk. Defendants had the means and the resources to perform their pharmacovigilance duties for the entire time Enbrel® has been on the market in the United States. Furthermore, Defendants had a duty to provide adequate instructions to manage or mitigate the known risks associated with the use of Enbrel® and failed to so instruct.

125. Defendants failed to comply with the FDA post-marketing reporting requirements under 21 C.F.R. § 314.80(c) by, inter alia, failing to report each adverse drug experience concerning Enbrel® that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days after initial receipt of the information by defendant, failing to promptly investigate all adverse drug experiences concerning Enbrel® that are the subject of these post-marketing 15-day Alert reports, failing to submit follow-up reports within 15 calendar days of receipt of new information or as requested by FDA, and, if additional information was not obtainable, failing to maintain records of the unsuccessful steps taken to seek additional information. Defendants further failed to meet the periodic reporting requirements of 21 C.F.R. § 314(c), 21 C.F.R. § 314.81, and 21 C.F.R. § 312.33.

126. Defendants failed to develop and act upon written procedures for the surveillance, receipt, evaluation, and reporting of post-marketing adverse drug experiences to FDA.

127. Defendants failed to adequately instruct doctors on patients on risk mitigation concerning infections associated with the use of Enbrel®.

128. Despite the availability of publicly available adverse event information from the FDA, Defendants failed to make adequate use of this information including information on the relationship between other TNF inhibitors and infections. Defendants failed to promptly review all adverse drug experience information concerning the risk of infections associated with the use of Enbrel®.

129. Defendants' failure to perform adequate pharmacovigilance and failure to comply with the post-marketing requirements of FDA regulations is evidence of Defendants' negligence.

130. Had Defendants properly conducted pharmacovigilance as required, the totality of the information available, much of which was in the exclusive possession of Defendants, would have shown that the risks of diabetes through the use of LIPITOR® warranted the inclusion of a warning ion the package insert.

131. Despite the fact Defendants knew or should have known that LIPITOR® caused unreasonable, dangerous side effects which many users would be unable to remedy by any means, they continued to market LIPITOR® to physicians, including Plaintiffs' physicians, and consumers, including Plaintiffs, when there were safer alternative methods of treatment.

132. Defendants knew or should have known that consumers such as Plaintiffs would suffer injury or death as a result of Defendants' failure to exercise ordinary care as described above.

133. As a direct and proximate result of Defendants' negligence and wrongful conduct, Plaintiffs were injured as described above.

WHEREFORE, Plaintiffs demand judgment against Defendants in such an amount of compensatory and punitive damages as a jury deems reasonable, plus costs.

THIRD CAUSE OF ACTION

(Breach of Express Warranty)

134. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

135. Before Plaintiffs were first prescribed LIPITOR® and during the period in which they

used LIPITOR®, Defendants expressly warranted that LIPITOR® was safe.

136. LIPITOR® did not conform to these express representations because LIPITOR® was not safe and had an increased risk of serious side effects, including diabetes, whether taken individually or in conjunction with other therapies.

137. As a direct and proximate result of this wrongful conduct, Plaintiffs were injured as described above.

WHEREFORE, Plaintiffs demand judgment against Defendants in such an amount of compensatory and punitive damages as a jury deems reasonable, plus costs.

FOURTH CAUSE OF ACTION

(Breach of Implied Warranty)

138. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

139. At the time Defendants packaged, labeled, promoted, marketed, advertised, sold, and/or distributed LIPITOR® for use by Plaintiffs, they knew of the use for which LIPITOR® was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

140. Plaintiffs reasonably relied upon the skill and judgment of Defendants as to whether LIPITOR® was of merchantable quality and safe and fit for its intended use.

141. Contrary to such implied warranty, LIPITOR® was not of merchantable quality or safe or fit for its intended use, because the product was and is unreasonably dangerous and unfit for the ordinary purpose for which it was used as described above.

142. As a direct and proximate result of the Defendants' wrongful conduct, Plaintiffs were injured as described above.

WHEREFORE, Plaintiffs demand judgment against Defendants in such an amount of compensatory and punitive damages as a jury deems reasonable, plus costs.

FIFTH CAUSE OF ACTION

(Fraud)

143. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

144. Before Plaintiffs were prescribed LIPITOR® and during the period in which they took LIPITOR®, Defendants made false representations regarding the safety and efficacy of LIPITOR®. Defendants knew that its representations regarding the safety of LIPITOR® were false.

145. Defendants' representations regarding the safety and efficacy of LIPITOR® were made with the intent of misleading Plaintiffs and Plaintiffs' physicians in relying upon those representations, and Plaintiffs and Plaintiffs' physicians were justified in relying, and did, in fact, rely, upon such misrepresentations.

146. Defendants' misrepresentations regarding the safety and efficacy of LIPITOR® were material. Plaintiffs would not have ingested LIPITOR® for treatment and control of high cholesterol had they been made aware of the true risks associated with using LIPITOR®, including but not limited to diabetes.

147. Defendant failed to disclose to U.S. healthcare professionals and patients that LIPITOR® was an important identified risk of Diabetes. Given that the label does not provide any warning concerning the risk of Diabetes nor any information concerning managing the risks of LIPITOR®, these omissions contributed to Plaintiffs' injuries.

148. As a direct and proximate result of Defendants' misrepresentations, Plaintiffs were injured as described above.

WHEREFORE, Plaintiffs demand judgment against Defendants in such an amount of compensatory and punitive damages as a jury deems reasonable, plus costs.

SIXTH CAUSE OF ACTION

(Fraudulent Concealment)

149. Plaintiffs re-allege all allegations of the Complaint as if set out here in full.

150. Before Plaintiffs were prescribed LIPITOR® and during the period in which they took LIPITOR®, Defendants concealed material facts regarding the safety and efficacy of LIPITOR®, more specifically, that LIPITOR® caused diabetes. Defendant had a duty to disclose this

information to prescribing physicians and the general public, including Plaintiffs.

151. Defendant failed to disclose to U.S. healthcare professionals and patients that LIPITOR® was an important identified risk of Diabetes. Given that the label does not provide any warning concerning the risk of Diabetes nor any information concerning managing the risks of LIPITOR®, these omissions contributed to Plaintiffs' injuries.

152. Defendants' concealment of material information regarding LIPITOR® was done with the intent to mislead Plaintiffs and Plaintiffs' physicians, and Plaintiffs and Plaintiffs' physicians were justified in reliance on Defendants' concealment.

153. As a direct and proximate result of Defendants' concealment of material facts, Plaintiffs were injured as described above.

WHEREFORE, Plaintiffs demand judgment against Defendants in such an amount of compensatory and punitive damages as a jury deems reasonable, plus costs.

SEVENTH CAUSE OF ACTION AGAINST DEFENDANTS CONSUMER FRAUD - VIOLATION OF GBL §§ 349 and 350

154. Plaintiffs incorporate by reference the paragraphs above, as though fully set forth herein.

155. Defendants acted, used and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations, and knowingly concealed, suppressed and omitted material facts with the intent that consumers, and their physicians and medical providers, rely upon such concealment, suppression, and omission, in connection with the sale, advertisement and promotion of Lipitor, in violation of all applicable state consumer fraud statutes, for the purpose of influencing and inducing physicians and medical providers to prescribe Lipitor to patients and consumers herein. By reason of the Defendants' unconscionable, deceptive and fraudulent acts and practices, and false pretenses, false promises, and

misrepresentations, reasonable patients/consumers acting reasonably, herein, were caused to suffer ascertainable loss of money and property and actual damages.

156. Defendants engaged in consumer-oriented, commercial conduct by selling and advertising the subject product.

157. Specifically, in the 2007-2008 timeframe, Defendants used Robert Jarvik to suggest that he was glad to use Lipitor as a "doctor". Jarvik, although having received a degree in medicine from the University of Utah, was not licensed to practice medicine. Referring to himself as a doctor clearly left the public with the impression that he was a practicing physician. After much criticism including congressional scrutiny, Pfizer withdrew the ads. Pfizer's use of these advertising tactics were deceptive and at least one survey showed that it was very effective[2].

158. Defendants misrepresented and omitted material information regarding the subject product by failing to disclose known risks.

159. Defendants misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the subject product, in violation of New York General Business Law ("GBL") §§ 349 and 350.

160. New York has enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. Defendants violated these statutes by knowingly and falsely representing that the subject product was fit to be used for the purpose for which it was intended, when Defendants knew it was defective and dangerous, and by other acts alleged

[2] See https://www.consumerreports.org/cro/news/2008/03/lipitor-the-controversial-ad-proves-highly-effective/index.htm.

herein.

161. Defendants engaged in the deceptive acts and practices alleged herein in order to sell the subject product to the public.

162. As a direct and proximate result of Defendants' violations of GBL §§ 349 and 350, Plaintiffs have suffered damages, for which they are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs, and reasonable attorneys' fees.

163. As a direct and proximate result of Defendants' conduct, Plaintiff's used Lipitor and suffered serious physical injury and economic loss.

164. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

165. Plaintiffs seek actual and punitive damages as well as reasonable attorneys' fees and costs from Defendants as alleged herein.

WHEREFORE, by reason of the foregoing, Plaintiffs were damaged in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition, Plaintiffs demand judgment against Defendants for damages, individually in accordance with any percentage of fault assigned to them, and/or jointly and severally, as the law may allow, and award relief as determined by all of the evidence, as well as all costs of this action and a trial by jury of all issues to be tried.

NINTH CAUSE OF ACTION

(Loss of Consortium)

THIS CAUSE OF ACTION APPLIES TO THE FOLLOWING PLAINTIFFS: ARNOLD BUONAMANO, EDWARD MEIDL, RONNIE SCOTT, BRYAN

AXELROD, and TOMMIE A. RHETT (Hereinafter referred to as "LOC PLAINTIFFS")

166. Plaintiffs hereby incorporate by reference as if fully set forth herein, each and every allegation contained in the foregoing paragraphs.

167. As a proximate result of the personal injuries suffered by LOC PLAINTIFFS, as described in this complaint, LOC PLAINTIFFS has been deprived of the benefits of their marriage including her love, affection, society, and consortium, and other wifely duties and actions. LOC PLAINTIFFS were provided with all of the benefits of a marriage between husband and wife, prior to her ingestion of LIPITOR by their respective Plaintiff wives and the resulting injuries described herein.

168. LOC PLAINTIFFS have also suffered the permanent loss of their respective Plaintiff wives' daily and regular contribution to the household duties and services, which each provides to the household as husband and wife.

169. LOC PLAINTIFFS have also incurred the costs and expenses related to the medical care, treatment, medications, and hospitalization to which their respective Plaintiff wives were subjected for the physical injuries she suffered as a proximate result of her ingestion of LIPITOR. LOC PLAINTIFFS will continue to incur the future costs and expenses related to the care, treatment, medications, and hospitalization of their respective Plaintiff wives due to her injuries.

170. LOC PLAINTIFFS have suffered loss of consortium, as described herein, including the past, present, and future loss of their wives' companionship, services, society, and the ability of their wives to provide LOC PLAINTIFFS with the benefits of marriage, including *inter alia*, loss of contribution to household income and loss of household services, all of which has resulted in his pain, suffering, and mental and emotional distress and worry.

WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants as follows:

1. For general (non-economic) damages according to proof at the time of trial;
2. For special (economic) damages according to proof at the time of trial;
3. For medical, incidental, and hospital expenses according to proof;
4. For restitution;
5. For punitive damages;
6. For pre-judgment and post-judgment interest as permitted by law;
7. For cost of suit incurred herein as permitted by law;
8. For such other and further relief as this Court may deem proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all issues so triable.

Dated: October 30, 2019

Respectfully submitted,

Excolo Law, PLLC

By: /s Keith Altman
Keith Altman

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